

K080606

AUG - 7 2008

**510(K) Summary (K08606) Powdered Latex Patient
Examination Glove with Protein Label Claims (300 Micrograms or
less)**

Name Alatech Healthcare LLC
1600, State Docks Rd,
Eufaula
Alabama 36027
U.S.A.

Phone Number (334) 688-8520

Fax (334) 688- 8521

Registration Number 3005627398

Activity of Applicant Manufacturer

Contact Person at Firm Neil Anderson RAC

Phone Number (334) 688- 8520

Fax (334) 688-8521

Email raexpirt@yahoo.com

Truthful and Accurate Statement

See Appendix I

Indications for Use

See Appendix II

Name and Location of Actual Manufacturer

Alatech healthcare LLC
1600, State Docks Road
Eufaula
Alabama 36027
USA

Phone Number (334) 688-8520

Fax (334) 688-8521

Label, Labeling and Advertising

See Appendix III

Device Classification

Class 1

Substantial Equivalence device Description

Patient Examination Glove, Powdered (with protein labeling claims claims 300 micrograms or less)

Predicate device K050527 Powdered Latex Examination Glove with Protein Labeling Claim,(300 micrograms or less) Manufacturer—

SPI Gloves, 5 Persiaran Greentown 8, Greentown Business Center, 39450 Ipoh, Perak, Darul Ridzuan, MALAYSIA

Product Code Latex 80-LYYSpecifications

Overall Length	230 mm minimum
Width	95 mm minimum (for medium Glove)
<u>Palm Thickness</u>	0.08 mm minimum
<u>Finger Thickness</u>	0.08 mm minimum
<u>Tensile Strength</u>	18 MPa minimum (before aging)
<u>Tensile Strength</u>	14 MPa minimum (after aging)
<u>Ultimate Elongation</u>	650% minimum (before aging)
<u>Ultimate Elongation</u>	500% minimum (after aging)
<u>Pinhole AQL</u>	2.5 (@70C for 7 days)

The data for this examination glove meets all of the current specification listed under ASTM Standard Specification D3578-05

Specialty, Chemotherapy Gloves

These gloves are not claimed to be for Specialty or Chemotherapy use.

Former Release Powder or Chemical

None used.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Neil Anderson R.A.C
Manager of Regulatory Affairs
Alatech Healthcare, LLC
1600 State Docks Road
Eufaula, Alabama 36027

AUG - 7 2008

Re: K080606

Trade/Device Name: Powdered Latex Patient Examination Glove with Protein Label
Claims (300 micrograms or less)

Regulation Number: 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I

Product Code: LYY

Dated: July 11, 2008

Received: July 21, 2008

Dear Mr. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mamuel's Lin, and for H".

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Appendix II

Indications for Use

Applicant Name Alatech Healthcare LLC
510(k) Number K080606
Device Name Powdered Latex Patient Examination Glove with Protein Label Claims (300 micrograms or less)

A powdered Patient Examination Glove is a disposable device made of natural rubber latex or synthetic material that bears powder to facilitate donning and is intended to be worn on the hand or finger(s) for medical purposes to provide a barrier against potentially infectious materials and other contaminants.

Prescription use _____
(21CFR 801 subpart D)

Over the Counter X
(21CFR subpart C)

Concurrence of CDRH Office of Device Evaluation.

Shirley H. Murphy MD
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 080606